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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/534,160	05/05/2005	Francois Jean-Charles Natt	DC/4-32768A	9963
75074	7590	01/11/2008		
NOVARTIS INSTITUTES FOR BIOMEDICAL RESEARCH, INC. 400 TECHNOLOGY SQUARE CAMBRIDGE, MA 02139				
			EXAMINER MCINTOSH III, TRAVISS C	
			ART UNIT 1623	PAPER NUMBER
			MAIL DATE 01/11/2008	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.

10/534,160

Applicant(s)

NATT ET AL.

Examiner

Traviss C. McIntosh

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 10 October 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-15 and 17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4,8-10,15 and 17 is/are rejected.
- 7) ☒ Claim(s) 5-7 and 11-14 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>10/10/07</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

The Amendment filed 10/10/2007 has been received, entered into the record, and carefully considered. The following information provided in the amendment affects the instant application by:

Claims 1-6, 8, 11, 14-15, and 17 have been amended.

Claim 16 has been canceled.

Remarks drawn to rejections of Office Action mailed 4/6/2007 include:

112 2<sup>nd</sup> paragraph rejections: which have been overcome by applicant's amendments and have been withdrawn.

An action on the merits of claims 1-15 and 17 is contained herein below. The text of those sections of Title 35, US Code which are not included in this action can be found in a prior Office action.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4, 8-10, 15 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Gunderson et al. (Chloromethoxysilanes as Protecting Reagents for Sterically Hindered Alcohols), Acta Chemica Scan. 43(198) pp. 706-709) and Pitsch et al. (Reliable Chemical Synthesis of Oligoribonucleotides", Helvetica Chemica Acta, vol. 84(2001) 3773-3795.

The claims of the instant application are drawn to 2'-protected ribonucleoside derivatives which have a protecting group which comprises a tertiary carbon atom or hetero atom bonded directly to the Si-atom. Dependent claims limit the tertiary C-atom to have 4-24 C-atoms; to optionally be tert-butyl; or 1,1-dimethyl-ethyl, which is seen to be the same thing as tert-butyl.

The instant application additionally claims methods of making the claimed protected compounds via a halogenation reaction or electrophilic activation of the ribonucleotide with the protecting group.

Pitsch et al. disclose methods of synthesizing ribonucleotides with halogenation reactions (scheme 2). Pitsch use a protecting group which does not have a tertiary carbon atom or hetero atom bound to the Si-atom. Their protecting groups comprise triisopropylsilyl groups. What is not taught is the tertiary carbon atom attached to the Si-atom.

Gunderson et al. teaches protecting groups for alcohols are tert-butyldimethylsilyloxy groups. Gunderson states that the protecting group is stable to normal alkylation processes and organometallic reagents, and is readily removed by fluoride-ion cleavage of the Si-O bond at ambient temperature (see page 706, column 1).

It would have been obvious to one of ordinary skill in the art at the time of the invention to use the protecting groups of Gunderson et al. in the methods and on the compounds of Pitsch et al. with these references before them. Pitsch et al. teach to protect the 2'-position with various protecting groups, and Gunderson et al. teach that their groups are effective in protecting OH groups. One would have had a reasonable expectation of success as the protecting groups are taught to be added and removed easily with normal reactions. Moreover, it is noted that the recent KSR decision forecloses the decision that a teaching/suggestion/motivation be found in the art.

*Conclusion*

Claims 5-7 and 11-14 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 10/10/2007 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609.04(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Traviss C. McIntosh whose telephone number is 571-272-0657. The examiner can normally be reached on M-F 9:30-6:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Traviss McIntosh  
January 7, 2008

Shaojia A. Jiang  
Art Unit 1623  
Supervisory Patent Examiner

A handwritten signature in black ink, appearing to read 'SAJ 1/7/08', is written over a horizontal line.